cardiox

510(k) SUMMARY
Cardiox™ Flow Detection System™, Model 99

Submitter's Name, Address, Telephone Number, Contact Person

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NOV 05 2013

Date Prepared: 06/24/2013

Name/Address of Sponsor:

Cardiox Corporation
4100 Horizons Drive, Suite 100
Columbus, OH 43220

Device Name:

Trade Name: Cardiox™ Flow Detection System™, Model 99
Common or Usual Name: Single-function, preprogrammed computer
Classification Name: Single-function, preprogrammed diagnostic computer (21 CFR 870.1435)

Predicate Devices:

Predicate Device Trade Name	Predicate Device Manufacturer
• Nihon Kohden MLC-4200 Cardiac Output Computer	Nihon Kohden
• Nihon Kohden MLC-4100 Cardiac Output Computer	Nihon Kohden

Intended Use / Indications for Use:

Indication for Use:

The Cardiox Flow Detection System Model 99 provides a fluorescent ICG indicator dye dilution curve for cardiac output in patients with known or suspected circulatory pathway abnormalities. The system is not designed to produce a definitive interpretation or exhaustive evaluation of a patient's circulatory pathway. Rather, it is intended to be used as a support tool in conjunction with other clinical and diagnostic findings. This device is only intended for use on patients that weigh more than 10kg.

Intended Use:

The Cardiox™ Flow Detection System™ (FDS™) Model 99 is intended to be used by medical professionals interested in detecting ICG in the peripheral vasculature, and evaluating blood flow through the heart and circulatory system. The Cardiox FDS Model 99 provides graphical display of indicator dye dilution curves using Indocyanine Green (ICG) as the indicator dye.

Device Description:

The Cardiox Flow Detection System (FDS) Model 99 utilizes near infra-red (NIR) spectrophotometry to transcutaneously detect the presence and relative concentration of indocyanine green dye (ICG) in blood vessels located at the scaphoid fossa of the ear.

The indicator dye, ICG, is injected into a peripheral antecubital vein of the patient while the patient optionally blows into the ValsalvaSure™ mouthpiece. The exhalation by the patient into the mouthpiece (i.e., performing a Valsalva maneuver) is available to provide conditions that may expose abnormal blood flow. The ValsalvaSure maneuver creates a pressure differential resulting in a right-to-left flow of blood between the atria, which results in a right-to-left-shunt (RLS) through any existing Atrial Septal Defect (ASD) and/or patent foramen ovale (PFO). The RLS allows blood to flow directly from the right atrium of the heart to the left atrium of the heart without passing through the lungs. The optical sensors in the Cardiox Earpads measure the relative concentration (i.e., fluorescence signal level) of ICG in the bloodstream as a function of time. Once captured by the photodiodes, the measured fluorescence signal is transmitted to the FDS Monitor.

In a subject with a normal circulatory pathway, the ICG is injected into an antecubital vein, travels through the heart and lungs then into the arterial vasculature, and is detected at the scaphoid fossa of the ear. The magnitude of the ICG curve peak amplitude is measured and displayed by the Cardiox FDS monitor, and is referred to as the Major Curve Peak Amplitude. In a subject with an abnormality in the circulatory pathway, such as a RLS, some of the ICG dye arriving in the right atrium follows a shorter pathway between the right atrium and left atrium, instead of traveling through the anatomically longer pathway through the lungs. This fraction of ICG dye that passes through an anatomical abnormality arrives at the scaphoid fossa of the ear in advance of the main bolus of ICG dye that follows the normal circulatory pathway through the lungs. The magnitude of the ICG curve peak amplitude associated with the earlier arrival of dye is measured and displayed by the Cardiox FDS monitor, and is referred to as the Minor Curve Peak Amplitude.

The report generated by the Cardiox FDS Model 99 identifies the Major Curve and Minor Curve Peak Amplitudes.

The Cardiox™ Flow Detection System™ Model 99 consists of the following components and accessories:

CARDIOX FDS REUSABLE SYSTEM AND ACCESSORIES
Cardiox Flow Detection System, Model 99 Consisting of the following components and accessories:
• FDS Monitor, Model 99
• Cardiox Earpads
• Cardiox Headband
• Cardiox Flow Sensor Cable

CARDIOX FDS DISPOSABLE PROCEDURE KIT COMPONENTS	
1.	Cardiox FDS™ Flowset Disposable Injection Set
2.	Cardiox FDS™ Mouthpiece
3.	Syringe without Needle 3 mL (x2
4.	Syringe without Needle 5 mL
5.	20 mL Syringe Luer-Lok™ Tip (x2)
6.	Blunt Fill Needle, 18 Gauge (x5)
7.	Blunt Fill Needle- Filter, 18 Gauge
8.	Shielded IV Catheter, 20 Gauge
9.	Utility Drapes
10.	IV Start Kit
11.	Akorn® IC-Green (indocyanine green for injection, USP) 25 mg vial
12.	Akorn® Aqueous Solvent 10mL ampule
13.	Hospira® 0.9% Sodium Chloride Injection

Technological Characteristics:

The Cardiox FDS Model 99 utilizes near-infrared (NIR) spectrophotometry to detect the presence of Indocyanine Green for Injection (ICG) dye in the peripheral vasculature. Spectrophotometry is the quantitative measurement of the reflection or transmission properties of a material as a function of wavelength.

The FDS Earpads™, including their fluorescence sensor arrays (FSA™), are used to measure and indicate the relative concentration (i.e., fluorescence signal level) of ICG dye in the bloodstream as a function of time. The Earpads contain two sets of three for a total of six coupled laser diode (LD) light sources and photodiodes. The Earpads are positioned on the surface of the subject's skin at the scaphoid fossa of each ear. When a predetermined dose of the ICG dye is injected into a peripheral antecubital vein in the human body, it is rapidly bound to plasma protein, and generates fluorescence in the NIR range (835 nm center wavelength in whole blood) when excited by light (785 nm wavelength) from the Earpads' LD light source.

The system's detector measures the time-varying intensity of emitted fluorescence photons over a predetermined time interval. The measured intensity of the emitted fluorescence photons is proportional to the concentration of the dye in the blood and can thereby provide an indicator dye-dilution curve that characterizes blood flow through the heart.

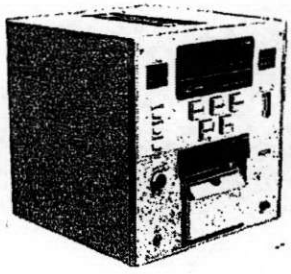
Once captured by the photodiodes, the measured fluorescence signal is transmitted from the FDS Earpads to the FDS Monitor for recording, displaying, and reporting the indicator dye-dilution curves to the clinician.

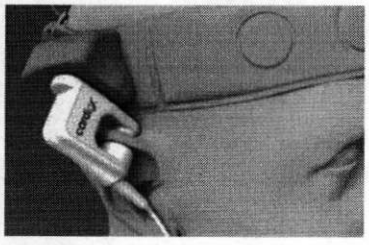
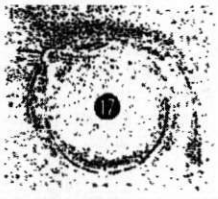
Abnormal characteristics in the circulatory system present as a distortion in the measured indicator dye dilution curve and can be characterized in terms of its minor peak amplitude relative to the major peak amplitude of the indicator dye dilution curve associated with cardiac output. ICG is FDA-approved and indicated for "determining cardiac output, hepatic function and liver blood flow, and for ophthalmic angiography."

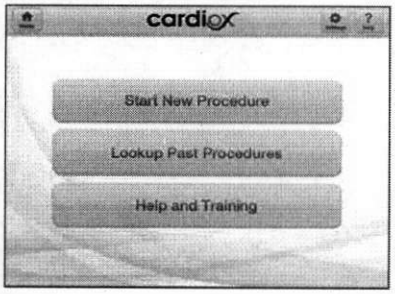
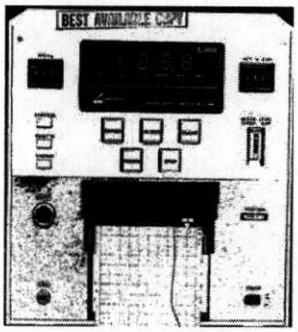
Comparison of Technical Characteristic between Cardiox™ FDS™ Model 99 and the Predicate Devices:

Feature/ Component	NEW DEVICE The Cardiox™ Flow Detection System™ Model 99	PREDICATE DEVICES Nihon Kohden America MLC-4200 & MLC-4100
Regulation Number	870.1435	870.1435
Classification Product Code	DXG	DXG
Manufacturer	Cardiox Corporation 4100 Horizons Drive Columbus OH 43220	Nihon Kohden (America), Inc. 530 Maple Avenue Torrance, CA 90503
Indications for Use	The Cardiox Flow Detection System Model 99 provides a fluorescent ICG indicator dye dilution curve for cardiac output in patients with known or suspected circulatory pathway abnormalities. The system is not designed to produce a definitive interpretation or exhaustive evaluation of a patient's circulatory pathway. Rather, it is intended to be used as a support tool in conjunction with other	The Nihon Kohden MLC-4200/MLC-4100 Cardiac Output Computer provides a non-invasive measurement and record of a dye concentration curve for investigation of intra-cardiac shunts and valvular regurgitation.

Feature/ Component	NEW DEVICE The Cardiox™ Flow Detection System™ Model 99	PREDICATE DEVICES Nihon Kohden America MLC-4200 & MLC-4100
	clinical and diagnostic findings. This device is only intended for use on patients that weigh more than 10kg.	
Intended Use	The Cardiox™ Flow Detection System™ (FDS™) Model 99 is intended to be used by medical professionals interested in detecting ICG in the peripheral vasculature, and evaluating blood flow through the heart and circulatory system. The Cardiox FDS Model 99 provides graphical display of indicator dye dilution curves using Indocyanine Green (ICG) as the indicator dye.	The Nihon Kohden MLC-4200/MLC-4100 constructs a curve representing Indocyanine Green for (ICG) dye concentration with respect to time (dye concentration curve). The device provides a record of the curve for analysis of circulatory system abnormalities.
Operating Technology	Infrared Spectrophotometry	Infrared Spectrophotometry
Operating Principle	Spectrophotometric ICG blood detection and measurement	Spectrophotometric ICG blood detection and measurement
Fluorescence Media	Indocyanine Green (ICG) Dye	Indocyanine Green (ICG) Dye
Technological Characteristics	The Cardiox Model 99 Flow Detection System (FDS) is used with Indocyanine-Green (ICG), a green dye that temporarily binds with serum albumin, its fluorescent agent. When a blood vessel is irradiated with 785 nm photons over a predetermined time interval, this dye fluoresces, emitting photons at wavelengths in the range of 830 to 840 nm. The system's detector measures the time-varying intensity of emitted fluorescence photons over a predetermined time interval. The measured intensity of the emitted fluorescence photons is proportional to the concentration of the dye in the blood and can thereby provide an indicator-dilution curve that	After a small amount (5mg) of Indocyanine-Green dye is injected into a vein, changes in its concentration are detected at a point in the arterial system. The dye is detected either by a small attachment to the ear or by cuvette through which the blood sample is drawn at a constant speed. Changes in the amount of dye in the blood are measured optically by passing light (805 and 900 nm for ear, 805 nm for cuvette) through the blood flowing in the ear or the cuvette and measuring the intensity of the transmitted light with a dye sensitive phototransistor. A dye concentration curve is constructed by capturing the concentration in relation to time.

Feature/ Component	NEW DEVICE The Cardiox™ Flow Detection System™ Model 99	PREDICATE DEVICES Nihon Kohden America MLC-4200 & MLC-4100
	characterizes blood flow through the heart. Abnormal characteristics in the circulatory system present as a distortion in the measured indicator-dilution curve and can be characterized in terms of its minor peak amplitude relative to the major peak amplitude of the indicator dye-dilution curve. ICG is FDA-approved and indicated for "determining cardiac output, hepatic function and liver blood flow, and for ophthalmic angiography."	Cardiac output is automatically computed by dividing the amount of dye injected into the vein by the area of the dye concentration curve. Cardiac output is presented in four digits with a maximum of 19.99. The dye concentration curve is recorded for investigation of intra-cardiac shunts and valvular regurgitation or for determining mean transit time and total circulating blood volume, etc. If an abnormality is present in the circulatory system between the point of injection and the sampling site, it is revealed by a distortion of the normal pattern of the curve. When coupled with a Thermodilution Amplifier, cardiac output data can be obtained via the thermodilution method.
Design Features	Single-function, preprogrammed diagnostic computer with a modern user-friendly touchscreen interface, complete with an on-screen keyboard to enter patient data for improved usability. 	Single-function, preprogrammed diagnostic computer 
Dimensions (l x w x h)	Flow Detection Monitor (10007): 10.5 in wide x 11.25 in. high x 10.5 in. deep Earpads (20001): 93 in. long (includes length of cable)	Main Unit (MLC-4200M): 300 mm x 300 mm x 300 mm Earpiece (TL-410S): 16 in. diameter, 70 in. length

Feature/ Component	NEW DEVICE The Cardiox™ Flow Detection System™ Model 99	PREDICATE DEVICES Nihon Kohden America MLC-4200 & MLC-4100
	Headband (20002): 29 in. long x 2 in. wide Flow Sensor Cable (20003): 72 in. long Flowset Disposable Injection Set (31039): 29 in. long Mouthpiece (31035): 52.5 in. long	Cuvette (TL-430S): 450 mm x 190 mm x 190 mm Thermodilution Amplifier (AF-410V): 300 mm x 85 mm x 300 mm
Power Source	Single Phase 100-240 VAC +/- 10%, 50/60 Hz +/- 1 Hz, < 100 W	100, 110, 117, 220 or 240 VAC + 10%, 50/60 Hz, 30VA
Safety Features	Class I Laser Power-on and background self-tests Automatic Valsalva relief mechanism Audible & visual cues, indications and alerts Detection of external component/connection status	Cuvette: patient circuit is electrically isolated from the chassis, and the DC motor, used for suction, is entirely isolated from the AC line. Alarms: Amplitude too high, area too large, abnormally small cardiac output, unstable baseline, pulsation superimposed
Patient Interface	Earpads  Extension Set for injection of ICG dye 	Earpads  Extension tube for injection of ICG dye  17 ' 3-way stopcock with extension tube

Feature/ Component	NEW DEVICE The Cardiox™ Flow Detection System™ Model 99	PREDICATE DEVICES Nihon Kohden America MLC-4200 & MLC-4100
Major Components	Cardiox Flow Detection Monitor Cardiox Earpads Cardiox Headband Cardiox Flow Sensor Cable Cardiox FDS Flowset Disposable Injection Set, 31039 Cardiox ValsalvaSure™ Mouthpiece, 31035	Main Unit MLC-4200M Earpiece, TL-410S Earpiece Control Box, JQ-410V Cuvette, TL-430S Thermodilution Amplifier, AF-410V
Convenience Kit	Yes - Part No. 31039	Yes – Part No. TL-410S
Invasiveness	Minimally invasive – peripheral catheter	Minimally invasive – peripheral catheter
Sterile Package	Patient blood contact components sterile	Patient blood contact components sterile
Sterilization Method	Extension Set – Ethylene Oxide Other components – EO or Gamma	Unknown
Re-Use	Single Use only	Single Use only
User Interface	Touch screen computer monitor 	Manual switches, buttons, and counters; digital numeric display 
Sampling	785 nm	805 and 900 nm

Feature/ Component	NEW DEVICE The Cardiox™ Flow Detection System™ Model 99	PREDICATE DEVICES Nihon Kohden America MLC-4200 & MLC-4100
Wavelength		
Output/ Presentation of Curves	Graphical representation of dye dilution curves	Graphical representation of dye dilution curves. Refer to MLC 4100 Operator's Manual.
Measuring Principle	Curves are analyzed: Major and Minor peaks of the curves are identified and measured	Curves are analyzed: Slope of curves are measured; specifically downward slope
Dye Concentration Curve Recording	Computer Display & Storage, with optional print out	Real-time strip chart print out

Performance Data

The commercially distributed Cardiox™ Flow Detection System™ conforms to the following standards:

Standard	Title
ISO 10993-1:2009	Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing Within a Risk Management Process
ISO 11135-1:2007	Sterilization of Health Care Products -- Ethylene Oxide -- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
ISO 11607-1:2009	Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
IS EN ISO 14971:2012	Medical Devices. Application of Risk Management To Medical Devices
IS EN ISO 15223-1:2012	Medical Devices. Symbols to be Used With Medical Device Labels, Labelling and Information to be Supplied. General Requirements
IEC 60529, Ed 2.1:2001-02	Degrees of Protection Provided by Enclosures (IP Code)
EN/ IEC 60601-1:2006	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance
EN/ IEC 60601-1-2:2007	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance –Collateral Standard. Electromagnetic Compatibility – Requirements and Tests
EN/ IEC 60601-1-6:2010	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance–Collateral Standard. Usability
IEC 60825-1 Ed. 2.0:2007	Safety Of Laser Products - Part 1: Equipment Classification and Requirements
IS EN/ IEC 62304:2006	Medical Device Software –Software Life Cycle Processes
EN/ IEC 62366:2008	Medical Devices. Application of Usability Engineering to Medical Devices

Substantial Equivalence

The **Cardiox™ Flow Detection System™ Model 99** is as safe and effective as the selected predicate devices, the Nihon Kohden MLC-4200/4100 Cardiac Output Computers. The Cardiox FDS Model 99 and the predicate devices have the same intended use and similar indications, technological characteristics and principles of operation.

The Cardiox FDS Model 99 device differs from the MLC-4200/4100 Cardiac Output Computer in that its primary function is to present and measure indicator dye dilution curves while the MLC-4200/4100 Cardiac Output Computer also presents and measures indicator dye dilution curves, it also produces a cardiac output value that captures the concentration of dye measured at the ear in relation to the dose of dye injected at the remote site.

These differences do not present any new issues of safety or effectiveness because the difference in the two technology's methods to measure the ICG dye concentration is not significant and does not have an impact on the performance of either device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 5, 2013

Cardiox Corporation
C/O Karen E. Matis, RAC, CCRA
Vice President, Quality and Regulatory Affairs
4100 Horizons Drive Suite 100
Columbus, OH 43220

Re: K122400
Trade/Device Name: Cardiox® Flow Detection System™ Model 99
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, preprogrammed diagnostic computer
Regulatory Class: Class II
Product Code: DXG
Dated: June 25, 2013
Received: June 26, 2013

Dear Ms. Matis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):__K122400_____

Device Name: Cardiox® Flow Detection System™ Model 99

Indications for Use:

The Cardiox Flow Detection System Model 99 provides a fluorescent ICG indicator dye dilution curve for cardiac output in patients with known or suspected circulatory pathway abnormalities. The system is not designed to produce a definitive interpretation or exhaustive evaluation of a patient's circulatory pathway. Rather, it is intended to be used as a support tool in conjunction with other clinical and diagnostic findings. This device is only intended for use on patients that weigh more than 10kg.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen R. Faris -S
Date: 2013.11.05 16:20:37 -05'00'